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Department of Obstetrics and Gynecology

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To whom it may concern:

Our practice strongly objects to the proposed rules entitled "Suitability Determination for Donors of Human Cellular and Tissue-Based Products." We object to these proposed rules for both scientific and pragmatic reasons.

We have never had a documented case of transmission of any infectious disease via an in vitro fertilization cycle in our program. In fact, there is no evidence that HIV has ever been transmitted in any in vitro fertilization program.

Quarantining the embryos is likely to halve the pregnancy rate for egg donation in our program. Our delivery rate for a frozen embryo transfer resulting from an egg donation cycle is ~20%, compared with a 40-50% delivery rate per fresh embryo transfer in an egg donation cycle.

Freezing all embryos results in increased cost per cycle (\$1000 to freeze and thaw embryos per cycle in our program). An even greater impact on cost is the need to perform two cycles instead of one cycle to achieve an equivalent pregnancy rate. The cost of an egg donation cycle in our program is about \$12,000.

Due to a critical shortage of egg donors in our region of the country, we would not be able to meet the needs of couples who required additional cycles due to lower pregnancy rates. Current wait for an anonymous egg donor in our program is approximately one year. In some regions of the country, escalating reimbursement to egg donors has begun due to the shortage of suitable donors. A law requiring freezing of embryos is likely to worsen the problem of the egg donor shortage due to the increased demand for repeat cycles.

Finally, mandating that a couple wait 6 months before embryo transfer and forcing them to accept a lower pregnancy rate creates a huge emotional burden. This suffering is completely unjustified given the available scientific data.

Sincerely,

Valerie L. Baker, MD

Medical Director, ART program

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